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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,705	01/28/2002	Haruki Yamada	082368-000000US	1019

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EXAMINER

ZEMAN, ROBERT A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,705

Applicant(s)

YAMADA ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 5-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment and response filed on 12-8-2005 are acknowledged. Claims 1-4 have been amended. Claims 12-14 have been amended.

Newly submitted claims 12-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the elected invention is drawn to an adjuvant comprising a hydroxyl unsaturated fatty acid (Group I of the restriction requirement) whereas claims 12-14 are drawn to methods of enhancing the immunological activity of a vaccine which constitutes a group separate and distinct from the groups set forth in the restriction requirement.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-14 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Consequently, Claims 1-14 are pending; claims 5-14 are withdrawn from consideration. Claims 1-4 are currently under examination.

Priority

As applicant has not filed a translation of the certified copy of application filed in Japan on 3-3-1999, the priority date of 3-3-2000 will still be used with regard to the availability of art under 35 U.S.C 102.

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Objections Withdrawn

The objection to the specification for the use of the trademark Tween 80 is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "derivative thereof" is withdrawn in light of the amendment thereto.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "prepared from a medicinal plant" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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The provisional rejection of claims 1-4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/363,484 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to adjuvants comprising hydroxyl unsaturated fatty acids wherein said fatty acids have 18 carbon atoms that have a trihydroxy-monoene structure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It should be noted that Applicant did not respond to this rejection in his response.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-3 under 35 U.S.C. 102(a) as being anticipated by Lederer et al. (J. Agric. Food Chem. 1999, Vol. 47, pages 4611 –4620) is maintained for reasons of record.

Applicant argues:

1. The amended claims read on an 18 carbon hydroxyl unsaturated fatty acid and a pharmaceutically acceptable carrier.

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2. Lederer does not disclose the claimed 18 carbon hydroxyl unsaturated fatty acid and an acceptable pharmaceutically carrier

Applicant's argument has been fully considered and deemed non-persuasive.

The instant claims only require one of the components be a pharmaceutically acceptable carrier since the open "comprising" language is used. Consequently, since the 18-carbon hydroxyl unsaturated fatty acid is disclosed in combination with water, all the limitations of the instant claims have been met.

As outlined previously, Lederer et al. disclose an 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC search report, attached). The use of the descriptive term "adjuvant" is deemed to be an intended use and hence does not constitute a claim limitation. Consequently, Lederer et al. anticipates all the limitations of the rejected claims.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamberg et al. (Plant Physiology, 1996, Vol. 110, pages 807-815).

Applicant argues:

1. The amended claims read on an 18 carbon hydroxyl unsaturated fatty acid and a pharmaceutically acceptable carrier.
2. Hamberg does not disclose the claimed 18 carbon hydroxyl unsaturated fatty acid and an acceptable pharmaceutically carrier

Applicant's argument has been fully considered and deemed non-persuasive.

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The instant claims only require one of the components be a pharmaceutically acceptable carrier since the open “comprising” language is used. Consequently, since the 18-carbon hydroxyl unsaturated fatty acid is disclosed in combination with water, all the limitations of the instant claims have been met.

As outlined previously, Hamberg et al. disclose an 18-carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC search report, attached) wherein said fatty acid was isolated from *Avena sativa* seed homogenates. The use of the descriptive term “adjuvant” is deemed to be an intended use and hence does not constitute a claim limitation. Consequently, Hamberg et al. anticipates all the limitations of the rejected claims.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyaichi et al. (Natural Medicines 1995, Vol. 49 No. 1, pages 24-28).

Applicant argues:

1. The amended claims read on an 18 carbon hydroxyl unsaturated fatty acid and a pharmaceutically acceptable carrier.
2. Miyaichi does not disclose the claimed 18 carbon hydroxyl unsaturated fatty acid and an acceptable pharmaceutically carrier.
3. Miyaichi discloses the claimed 18 carbon hydroxyl unsaturated fatty acid as one of 21 compounds in a crude drug while the instant claims require said 18 carbon hydroxyl unsaturated fatty acid to be the sole active ingredient.

Applicant’s argument has been fully considered and deemed non-persuasive.

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With regard to Points 1 and 2, the instant claims only require one of the components be a pharmaceutically acceptable carrier since the open “comprising” language is used. Consequently, since the 18-carbon hydroxyl unsaturated fatty acid is disclosed in combination with water, all the limitations of the instant claims have been met.

With regard to Point 3, the amended claims recite the language “as an active ingredient” indicating the claimed composition can contain multiple active ingredients. Consequently, the cited reference anticipates all the limitations of the instant invention.

As outlined previously, Miyaichi et al. disclose an 18-carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3 (see STIC search report, attached) wherein said fatty acid was isolated from *Sparganii rhizoma*. The use of the descriptive term “adjuvant” is deemed to be an intended use and hence does not constitute a claim limitation. Consequently, Miyaichi et al. anticipates all the limitations of the rejected claims.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Quinton et al. (Tetrahedron Letters, 1991, Vol. 32, No. 37, pages 4909-4912).

Applicant argues:

1. The amended claims read on an 18 carbon hydroxyl unsaturated fatty acid and a pharmaceutically acceptable carrier.
2. Quinton et al. Lederer does not disclose the claimed 18 carbon hydroxyl unsaturated fatty acid and an acceptable pharmaceutically carrier

Applicant’s argument has been fully considered and deemed non-persuasive.

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The instant claims only require one of the components be a pharmaceutically acceptable carrier since the open “comprising” language is used. Consequently, since the 18-carbon hydroxyl unsaturated fatty acid is disclosed in combination with water, all the limitations of the instant claims have been met.

As outlined previously, Quinton et al. disclose an 18 carbon hydroxyl unsaturated fatty acid with the structure (trihydroxy-monoene) recited in claim 3. The use of the descriptive term “adjuvant” is deemed to be an intended use and hence does not constitute a claim limitation. Consequently, Quinton et al. anticipates all the limitations of the rejected claims.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT A. ZEMAN
PATENT EXAMINER

February 28, 2006